Remarks

Applicant respectfully requests reconsideration of the present application, in view of the foregoing amendments and the reasons that follow. The specification has been amended to include a reference to applicant's prior application. Claims 1-32 are pending in this application.

Rejection under 35 U.S.C. 102(b)

Cousens *et al.*

The Office has maintained this rejection of claim 27, for the reasons set forth in the preceding Office action mailed May 13, 2003. In rebuttal to the applicant's arguments filed September 15, 2003, the Office action states at pages 6-7:

> It should be noted that the term "pharmaceutical" in "pharmaceutical composition" does not carry weight in 102(b) or 103(a) rejection of a product or composition claim. The specification of the present application fails to specifically define the phrase "pharmaceutically acceptable vehicle". Water and PBS buffer can be considered pharmaceutically acceptable vehicles and TE buffer or Tris buffer also can be considered a pharmaceutically acceptable vehicle. The use of Tris buffer in laboratory applications, such as in situ hybridization, in vitro diagnostic assays, and as an electrophoresis buffer, does not mean that Tris buffer can not be used as a pharmaceutically acceptable vehicle. It was very well known in the art to use TE buffer as DNA storage buffer. Further, since the term "pharmaceutical" in "pharmaceutical composition" does not carry weight in 102(b) or 103(a) rejection of a product or composition claims, it is irrelevant whether the yeast expression plasmid is used in a pharmaceutical composition or is used for preparing a polypeptide.

Applicant respectfully traverses this rejection.

By way of background, claim 27 recites a "pharmaceutical composition" that comprises a prescribed "a polynucleotide" and "a pharmaceutically acceptable vehicle for [that] polynucleotide." Since the specification does not expressly define "pharmaceutical composition," those words must be given their plain meaning. M.P.E.P. § 2111.01, *citing In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). According to DORLAND'S ILLUSTRATED

MEDICAL DICTIONARY (27th ed. 1988), "pharmaceutical" means "pertaining to pharmacy or to drugs," while "drug" means "any chemical compound that may be used on or administered to humans or animals." Cousens *et al.* discloses a yeast expression plasmid in TE buffer for only *in vitro* applications (see abstract and claim 1). The record is devoid of any evidence that a skilled person would have gleaned, from Cousens *et al.*, a composition used on or administered to humans or animals.

The Office argues that the term "pharmaceutical" in "pharmaceutical composition" carries no weight, but it cites no authority and, indeed, none exists for this proposition. On the contrary, controlling authority recognizes that a claim preamble may be limiting if "it recites essential structure or steps, or if it is necessary to give 'life, meaning, and vitality' to the claim." *Intirtool, Ltd. V. Texar Corporation*, Fed. Cir., No. 03-1394, 05/10/04, *quoting Catalina Mktg., Int'l v. Coolsavings.com*, 289 F.3d 801, 808 (Fed. Cir. 2002), and *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999).

A preamble is considered to give "life, meaning, and vitality" to a claim when, upon during prosecution, the preamble is invoked to distinguish the claimed invention from the prior art. *Id.*, *citing Catalina Mktg. v. Coolsavings.com*, 289 F.3d at 808-809. In the response filed September 15, 2003, applicant distinguishes claim 27 from Cousens *et al.* on the basis that "a yeast expression plasmid would not be used in a pharmaceutical composition, since the term ['pharmaceutical'] means that the composition is suitable for use *in vivo*" (page 6). Thus, the preamble recites "benefits or features" of the claimed invention ***and*** there is "clear reliance on those benefits or features as patentably significant." *Id.*, *citing Catalina Mktg. v. Coolsavings.com*, 289 F.3d at 809. "[S]uch reliance indicates use of the preamble to define, in part, the claimed invention." *Catalina Mktg.*, 289 F.3d at 808-809, *citing Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1375, 58 USPQ2d 1508, 1513 (Fed. Cir. 2001).

In addition, even if we were to assume, arguendo, that the term "pharmaceutical" has no impact on "pharmaceutical composition," the Office still would not have established that the TE buffer disclosed in Cousens *et al.* is a "pharmaceutically acceptable vehicle," as defined in the

application. That is, a "pharmaceutically acceptable vehicle can be a solid, liquid or gaseous material that can be used as a vehicle for administering a medicament *because the material is inert or otherwise medically acceptable, as well as compatible with the active agent, in a particular context of administration*" (specification at page 10).

To underscore this point, applicant submits the accompanying Rule 132 declaration by Dr. Anatoly Dritschilo, who attests that TE buffer and Tris buffer are neither inert nor otherwise medically acceptable. As "a medical doctor conversant in drug delivery technologies," Dr. Dritschilo is qualified to express the viewpoint of the person skilled in the art. Accordingly, the record establishes that neither TE buffer nor Tris would be deemed "pharmaceutically acceptable" for the purpose of the Office's stated rationale for rejection.

Hartman *et al.*

The Office has maintained an anticipation rejection of claims 27 and 28 over Hartman *et al.*, for the reasons set forth in the preceding Office action. In rebuttal to the applicant's arguments, filed September 15, 2003, the Office action states at pages 7-8:

> Since the buffer solution used to store plasmid is very well known in the art, it is common that the buffer solution containing the plasmid was not mentioned in journal publications. Hartman teaches preparation of plasmid pMSE-4 and transfection of E. coli cells with said plasmid. Therefore, plasmid pMSE-4 is stored in a DNA buffer solution and said buffer solution is considered a pharmaceutically acceptable vehicle.

Applicant respectfully traverses this rejection.

The present action does not identify which "buffer solution" the Examiner considers a pharmaceutically acceptable vehicle. The Office Action dated December 15, 2003, states at paragraph 6, however, that it "was very well known in the art to use TE buffer as DNA storage buffer." For the reasons set forth above, a TE buffer is not deemed a pharmaceutically acceptable vehicle.

Although Hartman *et al.* discloses potassium phosphate (pages 6, 13 and 19), potassium acetate (pages 13, 19), and Tris HCl (page 27), Hartman *et al.* fails to disclose any of these buffers in a pharmaceutical composition with the expression plasmid. Moreover, the Dritschilo declaration attests that none of these buffers is considered a pharmaceutically acceptable vehicle, because they are neither inert nor otherwise medically acceptable.

Thus, the evidence of record contravenes the position that Hartman *et al.* teaches a pharmaceutically acceptable vehicle.

Ishiye *et al.*

The Office maintains the rejection of claims 27 and 28 as being anticipated by Ishiye *et al.*, for the reasons set forth in the preceding Office action mailed May 13, 2003. In rebuttal to the applicant's arguments filed September 15, 2003, the Office action states at pages 7-8:

> Since the buffer solution used to store plasmid is very well known in the art, it is common that the buffer solution containing the plasmid was not mentioned in journal publications. Ishiye teaches preparation of plasmid pGGT298trp and transfection of E. coli HB101 cells with said plasmid. Therefore, plasmid pGGT298trp is stored in a DNA buffer solution and said buffer solution is considered a pharmaceutically acceptable vehicle.

Applicant respectfully traverses this rejection.

Although the Office action does not identify which "buffer solution" the Examiner considers a pharmaceutically acceptable vehicle, the Office Action dated December 15, 2003, states at paragraph 6 that "[i]t was very well known in the art to use TE buffer as DNA storage buffer." For the reasons set forth above, a TE buffer is not deemed a pharmaceutically acceptable vehicle.

While Ishiye *et al.* also discloses potassium phosphate (see page 236) and Tris HCl (see pages 236 and 238), Ishiye *et al.* fails to disclose the expression vector with any of these buffers in a pharmaceutical composition. Moreover, the Dritschilo declaration states that none of these

buffers are considered a pharmaceutically acceptable vehicle because they are neither inert nor otherwise medically acceptable.

Thus, the evidence of record fails to support that Ishiye *et al.* teaches a pharmaceutically acceptable vehicle.

Rejection under 35 U.S.C. 103(a)

The Office maintains the rejection of claims 27 and 29 as being unpatentable over Hartman *et al.* in view of Nabel *et al.*, for the reasons set forth in the preceding Office action mailed May 13, 2003. In rebuttal to the applicant's arguments filed September 15, 2003, the Office action states at pages 9-10:

> As discussed above, the term "pharmaceutical" in "pharmaceutical composition" does not carry weight in 102(b) or 103(a) rejection of a product or composition claim. The specification of the present application fails to specifically define the phrase "pharmaceutically acceptable vehicle". The buffer solution containing the plasmid taught by Hartman is considered a pharmaceutically acceptable vehicle. Hartman teaches construction of a plasmid pMSE-4 containing a human manganese superoxide dismutase (hMnSOD) coding region under the control of lamda P_L promoter, and use of said plasmid to transfect E. coli cells for producing recombinant hMnSOD. Nabel teaches using retrovirus, adenovirus, adenoviral conjugages, and cationic liposomes for delivery of foreign DNA into vascular cells *in vitro*. One of ordinary skill in the art at the time of the invention would have been motivated to substitute the plasmid as taught by Hartman with adenovirus vector or liposome as taught by Nabel in order to introduce the human MnSOD into target cells, such as vascular cell, in vitro with reasonable expectation of success.

Applicant respectfully traverses this rejection.

For the reasons set forth above, Hartman *et al.* fails to teach a pharmaceutically acceptable vehicle. Nabel *et al.* does not overcome the deficiencies of Hartman *et al.* since it discloses only *in vitro* delivery of adenovirus vector or liposome. Nabel *et al.* even states, on page 250, that "pharmacology or dose-response properties of recombinant gene expression have

not been investigated" and that "[i]t is not currently known how many cells must be transfected in an arterial segment in order to produce a desired biological effect."

Rejection under Judicially Created Doctrine of

Obviousness-type Double Patenting

U.S. Patent No. 5,599,712

Claims 1-32 are rejected as being unpatentable over claims 1-25 of U.S. Patent No. 5,599,712(A).

The Terminal Disclaimer filed July 24, 2002 obviates this rejection.

U.S. Patent No. 6,221,848

Claims 1-26 and 30-32 are rejected as being unpatentable over claims 1-23 of U.S. Patent No. 6,221,848.

The enclosed Terminal Disclaimer obviates this rejection.

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Based on the foregoing amendment and remarks, applicant respectfully requests withdrawal of all outstanding rejections. Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check

being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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